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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,853	09/24/2003	Dinah W. Y. Sah	A118 US	4306

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EXAMINER

WANG, CHANG YU

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,853

Applicant(s)

SAH, DINAH W. Y.

Examiner

Chang-Yu Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 17, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,10-12,27-38 and 57-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,5,10-12,27-38 and 57-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

1. On consideration, the previous restriction requirement is withdrawn.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 2 in part, drawn to a method for treating neuropathic pain due to diabetic neuropathy, classified in class 514, subclass 2, for example.
 - II. Claims 2 (in part), 27, 28, drawn to a method for treating neuropathic pain due to virus infection, classified in class 514, subclass 2, for example.
 - III. Claims 2 (in part), drawn to a method for treating neuropathic pain due to sciatica, classified in class 514, subclass 2, for example.
 - IV. Claims 29-33, drawn to a method for treating neuropathic pain due to administration of therapeutic agents, classified in class 514, subclass 2, for example.
 - V. Claims 34, drawn to a method for treating neuropathic pain due to injury associated with trauma, classified in class 514, subclass 2, for example.
 - VI. Claims 38, drawn to a method for treating phantom pain, classified in class 514, subclass 2, for example.
3. The inventions are distinct, each from the other because of the following reasons:
Inventions I-VI are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either

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not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the pathology and etiologies of neurological injury are very different from those of diabetes, virus infection. The patient populations in each pathological condition are also very distinct. For example, the health status, the medication, the diagnosis, and the physiological condition in patients with neural injury are very different from those with diabetes, virus infection, cancer and phantom pain. It requires different diagnoses, equipments, steps and treatments for these different groups of patients. Thus, Inventions I, II, III, IV, V and VI are patentably distinct.

4. Claims 1, 4, 5, 10-12, 35-37, 57-70 link(s) inventions I, II, III, IV, V and VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 4, 5, 10-12, 35-37, 57-70. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the

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claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

6. This application contains claims directed to the following patentably distinct species of the claimed inventions:

i. If Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of virus selected from A) herpes virus, B) HIV or C) papilloma virus as recited in claims 2 and 28 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claim 28 is generic.

ii. If Group IV is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for therapeutic agents selected from A) anti-cancer or B) anti-viral agents recited in claims 30-33 for prosecution on the merits to which the

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claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claim 29 is generic.

7. The species listed above are patentably distinct for the following reasons:

These species are distinct because they are different virus and different agents. Each specific species differs with respect to its composition, structural feature, function and use. For virus, the cell components and biological characteristics are very different in different virus. Consequently the responses to different virus are also distinct. The molecular mechanisms contributed to the action of each virus and disease are very different and so are the effects. In addition, for therapeutic agents, the compositions and structures and outcomes for anti-viral agents are different from those of anti-cancer agents. Thus, these species are patently distinct.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-VI and a single species from groups i-ii that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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14. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
July 31, 2006


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER